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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	MDL NO. 15-02641-PHX-DGC
This Document Relates to:	
MIICHELLE MERCURIO, Plaintiff, v. C. R. BARD, INC. and BARD PERIPHERAL VASCULAR INC., Defendants.	Case No. CV-15-1886-PHX-DGC **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER AND AFFIRMATIVE DEFENSES AND DEMAND FOR TRIAL BY JURY**

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (Bard and BPV are collectively "Defendants") answer the Complaint ("Plaintiff's Complaint") of Plaintiff Michelle Mercurio ("Plaintiff") as follows:

PARTIES

1. Defendants are without information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 Plaintiff's Complaint and, on that basis, deny them.

2. Defendants are without information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 Plaintiff's Complaint and, on that basis, deny them.

3. Defendants deny the allegations contained in Paragraph 3 Plaintiff's Complaint.

4. Defendants deny that Bard is a Delaware corporation. By way of further answer, Defendants admit that Bard is a New Jersey Corporation with its principal place of business in New Jersey. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including under the trademark G2® Express Filters. However, Defendants are without information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 4 of Plaintiff's Complaint.

5. Defendants admit that BPV is an Arizona Corporation. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants also admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark G2® Express Filter Systems. However, Defendants are without information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 5 of Plaintiff's Complaint.

6. Defendants deny the allegations contained in Paragraph 6 of Plaintiff's Complaint.

7. Paragraph 7 of Plaintiff's Complaint does not include any factual allegations and, as a result, requires no response by Defendants. However, to the extent Paragraph 7

purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

DEMAND FOR JURY TRIAL

8. Paragraph 8 of Plaintiff's Complaint does not include any factual allegations and, as a result, requires no response by Defendants. However, to the extent Paragraph 8 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. Defendants demand a trial by jury on all issues appropriate for jury determination.

JURISDICTION AND VENUE

9. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Western District of New York. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

10. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Western District of New York.

TAG-A-LONG ACTION

11. The allegations contained in Paragraph 11 of Plaintiff's Complaint are conclusions of law, requiring no response from Defendants. To the extent a response is required, Defendants admit that the Judicial Panel of Multidistrict Litigation recently consolidated certain claims related to Bard IVC filters into MDL No. 2461, the transferor court for which is the United States District Court for the District of Arizona and over which Judge David G. Campbell presides. Defendants do not dispute that this action may be properly transferred to MDL No. 2461.

GENERAL FACTUAL ALLEGATIONS

12. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 12 of Plaintiff's Complaint.

13. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 13 of Plaintiff's Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 13 of Plaintiff's Complaint and, on that basis, deny them.

14. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism and that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants are without information or knowledge sufficient to form a belief as to the allegations regarding what physicians may recommend and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 14 of Plaintiff's Complaint.

15. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism by being inserted into the inferior vena cava. Defendants deny any remaining allegations contained in Paragraph 15 of Plaintiff's Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the time frame when the first transvenous method of interrupting blood clots in the inferior vena cava was developed, the identity of manufacturers

of inferior vena cava filters, or the appropriate indications for those manufacturers' filters and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 16 of Plaintiff's Complaint.

17. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the time frame when optional or retrievable inferior vena cava filters were first introduced on the market or the identity of manufacturers of retrievable inferior vena cava filters and, on that basis, deny them. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademarks Recovery®, G2®, G2® Express, G2®X, Eclipse™ and Denali™ Filter Systems and that each of these filters is indicated for both retrievable and permanent placement. Defendants deny any remaining allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the scenarios for which the Recovery® Filter was cleared for use are legal conclusions to which no answer is required. To an extent a response is required, Defendants admit that the Recovery® Filter was intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism, but deny any remaining allegations contained in Paragraph 18 of Plaintiff's Complaint, including all subparts thereof.

19. Defendants deny the allegations contained in Paragraph 19 of Plaintiff's Complaint as stated.

20. Defendants deny the allegations contained in Paragraph 20 of Plaintiff's Complaint as stated.

21. Defendants deny the allegations contained in Paragraph 21 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002 and for retrievable

placement on July 25, 2003, pursuant to applications submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 21 of Plaintiff's Complaint.

22. Defendants deny the allegations contained in Paragraph 22 of Plaintiff's Complaint as stated.

23. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002 and for retrievable placement on July 25, 2003, pursuant to applications submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 23 of Plaintiff's Complaint.

24. Defendants admit that the Recovery® Filter was on the market in 2004. Defendants deny the remaining allegations contained in Paragraph 24 of Plaintiff's Complaint.

25. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 25 of Plaintiff's Complaint.

26. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of Plaintiff's Complaint regarding the typical practices of physicians, including physician methods for determining successful implantation of the Recovery® Filter and, on that basis, such allegations are denied. Defendants deny any remaining allegations of Paragraph 26 of Plaintiff's Complaint.

27. Defendants deny the Recovery® Filter System was unreasonably dangerous or defective in any manner. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well-documented that many instances of filter fracture and/or migration result in no complications whatsoever, but, rather, are completely asymptomatic. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 27 of Plaintiff's Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's Complaint. By way of further answer, Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well-documented that many instances of filter fracture and/or migration result in no complications whatsoever, but, rather, are completely asymptomatic. Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny any remaining allegations contained in Paragraph 28 of Plaintiff's Complaint.

29. Defendants admit that there are various well-documented complications that may occur as a result of the perforation of any inferior vena cava filter. Defendants further admit that it is well-documented that many instances of filter perforation result in no complications whatsoever, but, rather, are completely asymptomatic. Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny any remaining allegations contained in Paragraph 29 of Plaintiff's Complaint.

30. Defendants deny the allegations contained in Paragraph 30 of Plaintiff's Complaint, including any allegations contained in Footnote 1.

31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's Complaint.

32. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. Defendants deny the remaining allegations contained in Paragraph 32 of Plaintiff's Complaint.

33. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2®, G2®X, and Eclipse™ Filters were developed in furtherance of those efforts. Defendants deny the remaining allegations contained in Paragraph 33 of Plaintiff's Complaint.

34. Defendants deny the allegations contained in Paragraph 34 as stated. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter. Defendants deny any remaining allegations contained in Paragraph 34 of Plaintiff's Complaint.

35. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations of Paragraph 35 of Plaintiff's Complaint.

36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's Complaint.

37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's Complaint.

38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's Complaint.

39. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 39 of Plaintiff's Complaint.

40. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 40 of Plaintiff's Complaint.

41. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 41 of Plaintiff's Complaint.

42. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants admit the G2® Express Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining allegations contained in Paragraph 42 of Plaintiff's Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's Complaint.

44. Defendants admit the G2®X Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining allegations contained in Paragraph 44 of Plaintiff's Complaint.

45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's Complaint.

46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's Complaint.

47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's Complaint.

48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's Complaint.

49. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Eclipse™ Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations of Paragraph 49 of Plaintiff's Complaint.

50. Defendants admit that the Eclipse™ Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section

510(k) of the Food, Drug and Cosmetic Act in 2010. Defendants further admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Eclipse™ Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 50 of Plaintiff's Complaint.

51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's Complaint.

PLAINTIFFS' [SIC] SPECIFIC FACTUAL ALLEGATIONS

52. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52 of Plaintiff's Complaint and, on that basis, deny them.

53. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53 of Plaintiff's Complaint and, on that basis, deny them.

54. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 54 of Plaintiff's Complaint and, on that basis, deny them.

55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's Complaint.

CLAIM I

STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

59. Defendants incorporate by reference their responses to Paragraphs 1-58 of Plaintiff's Complaint as if fully set forth herein.

60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's Complaint.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's Complaint.

62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's Complaint.

CLAIM II

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

63. Defendants incorporate by reference their responses to Paragraphs 1-62 of Plaintiff's Complaint as if fully set forth herein.

64. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter sold to Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Express Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Express Filter System. Defendants deny any remaining allegations contained in Paragraph 64 of Plaintiff's Complaint.

65. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding any promotional or informational materials provided to Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that

its inferior vena cava filters include labeling and instructions for use. Defendants deny any remaining allegations contained in Paragraph 65 of Plaintiff's Complaint

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiff's Complaint.

67. Defendants deny the allegations contained in Paragraph 67 of Plaintiff's Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's Complaint.

CLAIM III

NEGLIGENCE

70. Defendants incorporate by reference their responses to Paragraphs 1-69 of Plaintiff's Complaint as if fully set forth herein.

71. The allegations contained in Paragraph 71 of Plaintiff's Complaint are conclusions of law that require no response from Defendants. To the extent a response is required, Defendants deny those allegations.

72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's Complaint.

CLAIM IV

BREACH OF EXPRESS WARRANTY

76. Defendants incorporate by reference their responses to Paragraphs 1-75 of Plaintiff's Complaint as if fully set forth herein.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's Complaint.

CLAIM V

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

82. Defendants incorporate by reference their responses to Paragraphs 1-81 of Plaintiff's Complaint as if fully set forth herein.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Express Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Express Filter System. Defendants deny any remaining allegations contained in Paragraph 83 of Plaintiff's Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiff's Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's Complaint.

CLAIM VI

BREACH OF IMPLIED WARRANTY OF FITNESS

88. Defendants incorporate by reference their responses to Paragraphs 1-87 of Plaintiff's Complaint as if fully set forth herein.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiff's Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of Plaintiff's Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiff's Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's Complaint.

CLAIM VII

VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349

93. Defendants incorporate by reference their responses to Paragraphs 1-92 of Plaintiff's Complaint as if fully set forth herein.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of Plaintiff's Complaint.

97. Defendants deny the allegations contained in Paragraph 97 of Plaintiff's Complaint.

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following Paragraph 97 and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph, including all sub-parts thereof.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

6. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq*., and other pertinent federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

8. If Plaintiff has been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

9. There was no defect in the product at issue with the result that Plaintiff is not entitled to recover against Defendants in this cause.

10. If there were any defect in the products – and Defendants deny that there were any defects – nevertheless, there was no causal connection between any alleged defect and the product on the one hand and any damage to Plaintiff on the other with the result that Plaintiff is not entitled to recover against Defendants in this cause.

11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to by other persons or entities that are severally liable for all or part of Plaintiff's alleged injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages.

12. Plaintiff's claims are barred to the extent that the injuries alleged in the Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a manner not intended by Defendants and over which Defendants had no control.

13. Plaintiff's claims are barred to the extent that the injuries alleged in the Plaintiff's Complaint were caused by a substantial change in the product after leaving the possession, custody, and control of Defendants.

14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or Defendants.

15. Plaintiff's claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.

16. Defendants neither had nor breached any alleged duty to warn with respect to the product, with the result that Plaintiff is not entitled to recover in this cause.

17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate warnings and instructions to learned intermediaries.

18. At all relevant times, herein, Plaintiff's physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of Plaintiff's alleged damages.

20. To the extent that injuries and damages sustained by Plaintiff, as alleged in Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were unknown, unknowable, or not reasonably foreseeable to Defendants.

21. Defendants believe, and upon that ground allege, that Plaintiff was advised of the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and

voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars in whole or in part the damages that Plaintiff seeks to recover herein.

22. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, and/or laches.

25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the doctrines of contributory and/or comparative negligence.

26. In the further alternative, and only in the event that it is determined that Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

27. Should Defendants be held liable to Plaintiff, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff from all collateral sources.

28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of claims, and the prohibition on double recovery for the same injury.

29. The injuries and damages allegedly sustained by Plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff over which Defendants had no control.

30. The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

31. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

32. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiff's defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq*. and comments thereto.

33. Plaintiff cannot show that any reasonable alternative design would have rendered the Recovery® Filter inferior vena cava filter device as alleged in Plaintiff's Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be identified by Plaintiff.

34. The device at issue was not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).

35. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

37. Plaintiff's alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.

38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the New York Constitution.

40. Regarding Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of

the United States of America, and similar provisions of the New York Constitution, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause

of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 5th day of November, 2015.

s/Richard B. North, Jr.
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 5, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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